

## Title (en)

Composition comprising an HMG-CoA inhibitor and a nicotinic acid compound for treating hyperlipidemia

## Title (de)

Zusammensetzung enthaltend einen HMG-CoA-Reduktasehemmer und eine Nikotinsäureverbindung zur Behandlung von Hyperlipidämie

## Title (fr)

Composition contenant un inhibiteur de réductase HMG-CoA et un composé d'acide nicotinique destiné au traitement d'hyperlipidémie

## Publication

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## Application

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## Priority

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## Abstract (en)

[origin: WO9906035A2] The present invention relates to solid pharmaceutical combinations for oral administration comprising nicotinic acid or a nicotinic acid compound or mixtures thereof in an extended release form and an HMG-CoA reductase inhibitor, which are useful for altering lipid levels in subjects suffering from, for example, hyperlipidemia and atherosclerosis, without causing drug-induced hepatotoxicity, myopathy or rhabdomyolysis. The present invention also relates to methods of altering serum lipids in subjects to treat, for example, hyperlipidemia in hyperlipidemics, lipidemia in normolipidemics diagnosed with or predisposed to cardiovascular disease, and atherosclerosis, by administering such oral solid pharmaceutical combinations once per day as a single dose during the evening hours, without causing drug-induced hepatotoxicity, myopathy or rhabdomyolysis, or without causing in at least an appreciable number of individuals drug-induced hepatotoxicity, myopathy or rhabdomyolysis to such a level that discontinuation of such therapy would be required. More particularly, the present invention concerns oral solid pharmaceutical combinations comprised of, for example, (1) an HMG-CoA reductase inhibitor for immediate or extended release, (2) nicotinic acid, a nicotinic acid compound or mixtures thereof, and (3) a swelling agent to form a sustained release composition for extended release of the nicotinic acid or nicotinic acid compound or mixtures thereof for nocturnal or evening dosing for reducing serum lipids and increasing HDL-cholesterol. In accordance with the present invention, and by way of example, a composition for oral administration during the evening hours to alter serum lipids comprised of nicotinic acid and hydroxypropyl methylcellulose in the form of an extended or sustained release tablet or caplet coated with a coating comprising an HMG-CoA reductase inhibitor in immediate release form is disclosed. Also in accordance with the present invention, the pharmaceutical combinations may include a nonsteroidal anti-inflammatory agent for reducing the capacity of nicotinic acid or nicotinic acid compounds to provoke flushing reactions in individuals.

## IPC 8 full level

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